

April 9, 2025

To

Listing Department,

NATIONAL STOCK EXCHANGE OF INDIA LIMITED

Exchange Plaza,

Bandra Kurla Complex, Bandra (E),

MUMBAI -400 051

To

The Corporate Relations Department

**BSE LIMITED** 

Phiroz Jeejeebhoy Towers, 25<sup>th</sup> floor, Dalal Street,

MUMBAI -400 001

Company Code No. AUROPHARMA

Company Code No. 524804

Dear Sir/ Madam,

Sub: Press Release – CuraTeQ Biologics completes a successful Phase 1 Pharmacokinetics study of Denosumab BP16, a proposed biosimilar to Prolia® and Xgeva®

We enclose a copy of the Press Release that is being issued by the Company informing that CuraTeQ Biologics Private Limited, a wholly owned subsidiary of the Company announcing that its denosumab biosimilar, BP16, has successfully met the primary endpoints in a comprehensive pharmacokinetic (PK) and pharmacodynamic (PD) study.

Please take the information on record.

Thanking you,

Yours faithfully,
For AUROBINDO PHARMA LIMITED

B. Adi Reddy Company Secretary

**Encl.: Press Release** 

**AUROBINDO PHARMA LIMITED** 

(CIN: L24239TG1986PLC015190)

www.aurobindo.com

Corp. Off.: Galaxy, Floors: 22-24, Plot No.1, Survey No.83/1, Hyderabad Knowledge City, Raidurg Panmaktha, Ranga Reddy District, Hyderabad – 500 032, Telangana, India. Tel: +91 40 6672 5000 / 6672 1200 Fax: +91 40 6707 4044.



#### Hyderabad, India, April 09, 2025

CuraTeQ Biologics completes a successful Phase 1 Pharmacokinetics study of Denosumab BP16, a proposed biosimilar to Prolia® and Xgeva®

CuraTeQ Biologics Private Limited, a wholly owned subsidiary of Aurobindo Pharma Ltd, is pleased to announce that its denosumab biosimilar, BP16, has successfully met the primary endpoints in a comprehensive pharmacokinetic (PK) and pharmacodynamic (PD) study. This study enrolled a total of 204 healthy volunteers into three groups to compare BP16 with the reference products, Prolia®, obtained from both the EU and US markets.

Dr. Arpitkumar Prajapati, Head of Clinical Sciences at CuraTeQ Biologics, stated, "The results from our study confirmed that BP16 exhibits a PK profile nearly identical to the reference products, achieving key bioequivalence parameters—maximum serum concentration and area under the curve—within the established bioequivalence range of 80 -125 percent. Additionally, BP16 demonstrated comparable pharmacodynamics, safety, and immunogenicity profiles to both EU and US versions of the reference product. The study, which included 204 subjects from Australia and New Zealand, successfully met all the predefined endpoints."

Denosumab works by specifically targeting the RANK ligand (RANKL), a critical protein in the lifecycle of osteoclasts, the cells that break down bone. Denosumab's ability to inhibit RANKL makes it highly effective in treating conditions linked to bone loss, such as osteoporosis in postmenopausal women, bone metastases from cancers, and cancer treatment-related bone health issues.

"With the positive Phase 1 study results, we are optimistic about our ongoing Phase 3 study. This study is progressing across multiple sites in the EU, focusing on women with postmenopausal osteoporosis, and we anticipate its completion by May/June 2025," said Dr. Disha Dadke, Head of R&D and Regulatory Sciences at CuraTeQ Biologics. "We aim to submit a Marketing Authorization application to CHMP/EMA in the third quarter of this fiscal year."

### **About CuraTeQ Biologics Private Limited**

CuraTeQ Biologics Private Limited (CuraTeQ), a wholly owned subsidiary of Aurobindo Pharma Limited, is a global biopharmaceutical company headquartered in Hyderabad, India. CuraTeQ's vision is to improve the wellbeing of patients suffering from debilitating illnesses by providing them access to high quality and cost-effective biosimilars. It is focused on developing biosimilars for the treatment of various cancers and autoimmune diseases. CuraTeQ's pipeline consists of fourteen biosimilars, primarily targeting the immunology and oncology segments. It has end-to-end capabilities in producing a full range of products from bulk drug substance to fill-finish and packaged drug products.

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#### **About Aurobindo Pharma Limited**

Aurobindo Pharma Limited (www.aurobindo.com), (NSE: AUROPHARMA, BSE: 524804, Reuters: ARBN.NS, Bloomberg: ARBP IN) is an integrated global pharmaceutical company headquartered in Hyderabad, India. The Company develops, manufactures, and commercializes a wide range of generic pharmaceuticals, branded specialty pharmaceuticals and active pharmaceutical ingredients globally in over 150 countries.

The company has 30 manufacturing and packaging facilities that are approved by leading regulatory agencies including USFDA, UK MHRA, EDQM, Japan PMDA, WHO, Health Canada, South Africa MCC, Brazil ANVISA. The Company's robust product portfolio is spread over seven major therapeutic/product areas encompassing CNS, Anti-Retroviral, CVS, Antibiotics, Gastroenterological, Anti-Diabetics and Anti-Allergic, supported by a strong R&D set-up.

To know more, please log on to www.aurobindo.com

For further information or queries, please contact:

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## Disclaimer:

This press release contains statements that may constitute "forward looking statements" including and without limitation, statements relating to product characteristics and uses, sales potential—and target dates for product launch, implementation of strategic initiatives, and other statements relating to our future business developments and economic performance. While these forward-looking statements represent our judgment and future expectations concerning the development of our business, a number of risks, uncertainties and other factors could cause actual developments and results to differ materially from our expectations. The company undertakes no obligation to publicly revise any forward-looking statements to reflect future events or circumstances and will not be held liable for any use of this information.

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